MAR 1 4 2014

K132393

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510 (k) Summary

November 25, 2013

ADDRESS	DENALI CORPORATION 134 Old Washington Street Hanover, MA 02339-1629
OWNER/CONTACT PERSON	Dr. Jan G. Stannard TEL: 781-826-9190 FAX: 781-826-4465 j.stannard@denalicorporation.com
TRADE NAME	CERCOM II
COMMON NAME	Resin Cement
CLASSIFICATION NAME	DENTAL CEMENT (21 CFR 872.3275, Product Code EMA)
REGISTRATION	3006367836
PREDICATE DEVICES	Cercom Cement/Denali Corporation - RelyX Cement/ESPE/3M Variolink Cement/Ivoclar - Calibra Cement/Dentsply - Nexus Cement/Kerr
EQUIVALENCE	The predicate products have been found substantially equivalent under the 510(k) premarket notification process as Class II Dental Devices under CFR EMA 872.3275, Dental Cement.
DEVICE DESCRIPTION	CERCOM II Cement is a self-adhesive cement recommended for the bonding of ceramic, metal and composite restorations.
INTENDED USE	CERCOM II Cement is a self-adhesive cement recommended for the bonding of ceramic, metal and composite restorations.
TECHNOLOGICAL CHARACTERISTICS	CERCOM II has the same technological characteristics (intended use, application mechanism) as the predicate device CERCOM, except that CERCOM II is a dual-cure cement. CERCOM II can set on its own as well as set with visible light cure.
SUBSTANTIAL EQUIVALENCE	CERCOM II Cement is substantially equivalent in design, composition, performance, intended use and effectiveness to the predicate cement products cited. This assessment is based upon a comparison of the physical characteristics, mechanisms of use description, intended use, composition, and mechanical properties of the cited predicate products.
SUMMARY CONCLUSIONS	CERCOM II Cement has been found to be substantially equivalent in design, composition, performance, intended use and effectiveness to the predicate cement products cited.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 14, 2014

Denali Corporation
Dr. Jan G. Stannard
134 Old Washington Street
Hanover, MA 02339-1629

Re: K132393
Trade/Device Name: CERCOM II Cement
Regulation Number: 21 CFR 872.3275
Regulation Name: Resin Cement
Regulatory Class: II
Product Code: EMA
Dated: December 4, 2013
Received: December 6, 2013

Dear Dr. Stannard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510 (k) Number 132393
(if known)

Device Name

CERCOM II Cement

Indications for Use:

CERCOM II Cement is a self-adhesive cement recommended for the bonding of ceramic, metal and composite restorations.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
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☒ Prescription Use (Per 21 CFR 801.109) or ☐ Over-The-Counter Use